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September 12, 2017

Dr. Scott Gottlieb
FDA Administrator
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Docket ID: FDA-2017-N-4515, International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Ocfentanil, Carfentanil, Pregabalin, Tramadol, Cannabidiol, Ketamine, and Eleven Other Substances; Request for Comments

Dear Dr. Gottlieb:

The U.S. Hemp Roundtable is grateful for the opportunity to comment on the referenced request for comments. The Roundtable, the industry's leading business advocacy association, represents nearly two dozen firms from across the country, and at each link of the hemp supply and sales chain – and boasts the ex officio membership of all the industry's major grassroots organizations.

We join to oppose any effort by the World Health Organization (WHO), the United Nations (UN), or the Food and Drug Administration (FDA) to place restrictions on the sale or distribution of hemp-derived cannabidiol (CBD). Hemp-derived CBD does not have the potential for abuse or addiction, there is no potential for diversion, and it has shown a wide array of benefits for the wellness of those that consume it. That CBD is included in a list of dangerous, addictive opioids is a source of deep concern for an industry that only promotes health and wellness. But we are hopeful that this discussion and opportunity for comment will help assure federal and international agencies of the value of CBD and other hemp-derived food products.

“Hemp” is the non-psychoactive version of cannabis that has clear benefits as a superfood. In 2003, the US Department of Health and Human Services (HHS) patented the cannabinoids found in hemp as “antioxidants and neuroprotectants.” We agree with the HHS decision to protect cannabidiol for Americans.

The United States is the largest importer of hemp products in the world. Why? Americans simply understand that hemp and hemp-derived products are helpful and healthful. How has our country responded? Activists have long lauded hemp's many beneficial products, but decades of activism did not bring the desired results.

In 2014, Congress passed a seminal piece of legislation addressing the federal disposition of Industrial Hemp and Hemp-derived products. Section 7606 of the Agricultural Act of 2014 (2014 Farm Bill)¹ defines ***“industrial hemp” as the plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.*** Sec. 7606 also allows for the federally legal growth, cultivation, and marketing of Industrial Hemp by states with an *Industrial Hemp Research Pilot Program* (IHRPP) or via an institution of higher education.

The 2014 Farm Bill paved the way for over 30 states to adopt legislation legalizing the cultivation of Industrial Hemp and creating an IHRPP. Subsequent legislation and regulation have been adopted at the federal and state levels--including Sections 538² and 773³ of the Consolidated Appropriations Act of 2017 (Public Law No: 115-31 (05/05/2017))--that clearly address the intended definition of Industrial Hemp and Hemp-derived products, such as CBD --cannabidiol. Additionally, the United States Department of Agriculture (USDA) has clearly opined that hemp and hemp-derived products (including CBD) are federally recognized, legal, and worthy of grants and funding through the auspices of National Institute of Food and Agriculture(NIFA)⁴.

Through the course of human history and in every corner of the globe, Hemp and Hemp derived products have been cultivated and consumed. Prior to the 1930's, hemp and hemp-derived products had been bought, sold, and transacted in the United States; yet a blanket ban on all things cannabis put a stop to this in the 1940's. In more recent times, farmers in the US have had the good fortune to be granted the ability--under a tight regulatory framework--to grow hemp and to provide the agricultural commodity basis for the mainstream access to all the beneficial aspects of the magnificent hemp plant.

The opportunity for hemp and hemp derived products to once again flourish fits into a global trend towards natural botanical products. This trend is reinforced by the actions of the giant pharmaceutical companies: they know that the profiteering from the sleight-of-hand

¹ http://www.votehemp.com/PDF/Pages_from_farm0127.pdf

² (Sec. 538) Prohibits DOJ or the DEA from using funds provided by this division in contravention of a provision of the Agricultural Act of 2014 that permits an institution of higher education or a state department of agriculture to grow or cultivate industrial hemp for research purposes.

³ (Sec. 773) Prohibits funds provided by this division from being used: (1) in contravention of a provision of the Agricultural Act of 2014 that permits an institution of higher education or a state department of agriculture to grow or cultivate industrial hemp for research purposes; or (2) to prohibit the transportation, processing, sale, or use of industrial hemp that is grown or cultivated in accordance with the Agricultural Act of 2014, within or outside the state in which it is grown or cultivated.

⁴ <https://www.gpo.gov/fdsys/pkg/FR-2016-08-12/pdf/2016-19146.pdf>

manipulations of natural botanical products is close to its end. The public good, nationally and globally, demands inexpensive access to beneficial food products. Many feel as we do that this should be a basic human right.

Across the world, botanical products have blossomed as the public has demanded access to beneficial compounds that are NOT pharmaceutical. Why? Since time immemorial, all peoples on all continents have used plants like hemp in various forms for beneficial reasons like food.

To quote Hippocrates: “ Let thy medicine be thy food, and thy food be thy medicine”. In a modern context: the public wants the access to all healthful foods, and the job of governmental forces is simply to determine the safety parameters for public consumption.

This is where the structural problems of the FDA are evident: there are rules and advantages given to the pharmaceutical companies, under the auspices of shepherding the public good, that inhibit the people from accessing historical botanicals.

For CBD derived from hemp, the argument about the public good boils down to psychoactivity. This is easy to address: in the US, legal hemp and hemp-derived products are not psychoactive and not controlled substances. Hemp is an agricultural commodity and hemp-derived products are food.

Unfortunately for the general public, greater clarification is needed.

In the US, cannabis has recently (as of 2014) been broken into two categories: marijuana (Recreational and Medical) and Industrial Hemp. Society demands hemp-derived products, and regulators fear THC. This is easy to understand. Hemp, low in the psychotoxic THC, meets a variety of needs that even conservative folks understand as clearly agricultural in nature. Hemp-derived products are similar to all other agricultural products. For example, Orange trees that provide Oranges (food), Orange Juice (beverage), Vitamin C (nutraceutical), and regulated pharma grade anhydrous citric acid all share the same origin. Similarly, non-GMO corn provides corn, feed, mash, tortillas, regulated ethanol, and regulated Bourbon.

The structure and nature of the FDA forces definition into Food, Drug, Supplements and the grey area of all the other products not classified. CBD produced from hemp is not a controlled substance, so it is clearly not a drug. The FDA, with antiquated rules that only benefit pharmaceutical companies, says that CBD is not a supplement. **That means CBD derived from hemp is food.**

It is our opinion to let the confusion over marijuana and psychoactive THC run its course. States will act, and at some point, the federal government will recognize that prohibition just makes criminal that which taxation makes legal and profitable. Like alcohol, a regulated distribution system will eventually emerge and evolve.

But CBD is not THC.

Many years ago, the FDA and various international organizations incorrectly used the term marijuana as a blanket definition for cannabis. This problematic nomenclature has caused decades of incorrect policy decisions including the FDA’s present stance on CBD derived from

hemp, because it has lumped it in with Marijuana. The result is everything dealing with Cannabis (hemp, etc) is now wholly dependent on the definition and scheduling of marijuana. This global mis-characterization of cannabis as marijuana has provided only confusion, leading to the current state of affairs:

- **Cannabis = hemp + marijuana**
- **THC is psychoactive and has many potential benefits.**
- **CBD is not psychoactive and has many benefits.**
- **Agricultural commodities, like hemp, offer the public many beneficial products.**
- **CBD, an agricultural product derived from hemp, is just that. Like broccoli and turmeric, CBD is just a food product.**

Recently, hemp oils high in cannabinoids such as CBD, have gained fame due to the amazing evidence of the miraculous neuroprotective impact on Charlotte Figi's life in Colorado, that was displayed to the world by CNN. Now, millions realize that these neuroprotective, antioxidant, and anti-inflammatory benefits extend to a variety of neurological disorders such as mild anxiety, pain from exercise-induced inflammation, and dozens of more applications.

However, these stories have been sensationalized and entwined with "marijuana", as this continues to happen, millions remain confused

It is therefore our position that:

1. The World Health Organization (WHO) should ease international restrictions on CBD and that the FDA should reconsider its position on CBD as a healthful food rather than a dangerous controlled substance due to its availability as an agricultural product;
2. National and international policy makers must continue to develop reasonable legislation on hemp and hemp derived products in the context of hemp as food. Doing so will ensure that consumers are protected, the industry's growth trajectory can continue, new investors will be attracted, jobs will be created, and safe and reliable products will reach the hands of consumers;
3. The economic benefits of hemp and hemp derived products should not be discounted.
4. There is no abuse liability and potential for diversion as it relates to hemp and hemp derived products, including CBD--a concern of many in law enforcement. Hemp is an agricultural commodity and a food product. Abuse and diversion would not result in much;
5. While we certainly support research and development on hemp-derived CBD products, any immediate change in its classification as an agricultural commodity will result in an inability for consumers to access end products and cause unnecessary economic ramifications.

We urge the FDA to carefully consider this matter and will make ourselves available as a resource to evolve this framework.

Sincerely,
/s
Brian Furnish
President

U.S. Hemp Roundtable